DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2014

Zimmer Dental, Inc.
Christina Boydston
Quality Manager
1900 Aston Ave.
Carlsbad, California 92008-7308

Re: K142082
Trade/Device Name: Zimmer 3.1mmD Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 28, 2014
Received: July 31, 2014

Dear Ms. Boydston,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any

Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142082

Device Name: Zimmer 3.1mmD Dental Implant System

Indications For Use:

Zimmer 3.1mmD Dental Implants are designed for use in the anterior maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. Zimmer 3.1mmD Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical). The Zimmer 3.1mmD Dental Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are used for attachment of restorations requiring off-axis correction. The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are designed to be used in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.

The 2.9mm Contour Abutment and the 2.9mm Contour Abutment, Straight Hex are used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single- or multiple-unit restoration. The 2.9mm Angled Contour Abutment and the 2.9mm Angled Contour Abutment, Straight Hex are designed to be used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single- or multiple-unit restoration.

The 2.9mm Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The 2.9mm Temporary Abutment can be used for cement-retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations.

The Ball Abutment is used for retaining overdentures or partial dentures when resilience and facilitated oral hygiene are desired.

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

The Healing Screw is used to seal the implant internal connection and separate it from the soft tissue which is sutured over the implant during healing.

The Retaining Screws are intended to be used for securing the temporary abutments, final abutments and impression transfers to the implant or implant analog. The long Retaining Screw is intended to be used with Temporary Abutments for fabrication of screw-retained provisional restorations and with Impression Transfers for direct impressions.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
760.431.7811 (fax)

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4150
Contact:	Christina Boydston
Date Prepared:	July 28, 2014

2. Device Name:

Trade Name:	Zimmer 3.1mmD Dental Implant
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Trade Name:	2.9mm Angled Abutment
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Angled Abutment, Straight Hex
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Contour Abutment
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Contour Abutment, Straight Hex
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Temporary Abutment
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Ball Abutment
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Healing Collar
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

Trade Name:	2.9mm Healing Screw
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Abutment, Implant, Dental, Endosseous

3. Predicate Device(s):

Predicate Device No. 1

Trade Name:	Tapered Screw-Vent Implant
510(k):	K011028, K013227, K061410, K072589, K101977, K111889
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 2

Trade Name:	Screw-Vent Dental Implant
510(k):	K011028, K013227, K061410
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 3

Trade Name:	Ospol Dental Implant System
510(k):	K070184
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 4

Trade Name:	Zimmer Dental Inc. 20° Angled Abutment
510(k):	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 5

Trade Name:	Zimmer Dental Inc. 3.5mm Hex-Lock Abutment
510(k):	K052600
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 6

Trade Name:	Zimmer Dental Inc. Temporary Plastic Abutment
510(k):	K092377
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 7

Trade Name:	Zimmer Dental Inc. Screw-Vent Ball Abutment
510(k):	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 8

Trade Name:	Zimmer Dental TSV Healing Collars
510(k):	K111852
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 9

Trade Name:	Zimmer Dental Surgical Cover Screw
510(k):	K011028
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Implant, Endosseous, Root-Form

4. Device Description:

The Zimmer 3.1mmD Dental Implant System consists of 3.1mm threaded endosseous dental implants, as well as prosthetic components, and ancillary components for placement and restoration of these implants. The prosthetic components include 2.9mm Angled Abutment, 2.9mm Angled Abutment, Straight Hex, 2.9mm Contour Abutment, 2.9mm Contour Abutment, Straight Hex , 2.9mm Temporary Abutment, and 2.9mm Ball Abutment. The 2.9mm Angled, 2.9mm Contour, and 2.9mm Temporary Abutments are made to

support single or multiple unit restorations. The 2.9mm Ball Abutments are made to support overdentures. The ancillary components for the Zimmer 3.1mmD Dental Implant System include 2.9mm Healing Collars and 2.9mm Healing Screws which are used during the healing process.

Zimmer 3.1mmD Dental Implant is an endosseous dental implant composed of titanium alloy. The implant body is designed for ease of implantation and with greater surface area for osseointegration. The implant surface is treated to facilitate osseointegration. In addition, the implant body is tapered with triple-lead threads. The Zimmer Dental 3.1mmD Dental Implant is currently offered in 3.1mm diameter in lengths of 8, 10, 11.5, 13, and 16mm. They include two different texturing configurations: full texture to the top of the implant and texture to 0.5mm from the top of the implant. In addition, both texturing configurations of the implant have coronal grooves on the collar to within 0.64mm of the top of the implant similar to the predicate #1: *Tapered Screw-Vent Implant* Dental Implant. The implant-abutment interface platform diameter will be offered in a size of 2.9mm. The new device will feature MTX surface equivalent to existing Zimmer Dental implants.

The Abutments, Healing Collars, and Healing Screw are titanium alloy devices that are made to mate with the Zimmer 3.1mmD Dental Implant, which is also made of titanium alloy. The abutments are designed for use as a terminal or intermediate abutment prostheses.

5. Indications for Use:

Zimmer 3.1mmD Dental Implants are designed for use in the anterior maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. Zimmer 3.1mmD Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical). The Zimmer 3.1mmD Dental Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex and are used for attachment of restorations requiring off-axis correction. The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are designed to be used in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.

The 2.9mm Contour Abutment and the 2.9mm Contour Abutment, Straight Hex are used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single- or multiple-unit restoration. The 2.9mm Angled Contour Abutment and the 2.9mm Angled Contour Abutment, Straight Hex are designed to be used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single- or multiple-unit restoration.

The 2.9mm Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The 2.9mm Temporary Abutment can be used for cement-retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations.

The Ball Abutment is used for retaining overdentures or partial dentures when resilience and facilitated oral hygiene are desired.

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

The Healing Screw is used to seal the implant internal connection and separate it from the soft tissue which is sutured over the implant during healing.

The Retaining Screws are intended to be used for securing the temporary abutments, final abutments and impression transfers to the implant or implant analog. The long Retaining Screw is intended to be used with Temporary Abutments for fabrication of screw-retained provisional restorations and with Impression Transfers for direct impressions.

Device Comparison:

Zimmer Dental believes the new devices presented in the Zimmer 3.1mmD Dental Implant System to be substantially equivalent to their respective predicate. Furthermore, Zimmer Dental believes the Zimmer 3.1mmD Dental Implant system to be substantially equivalent to the previously cleared Tapered Screw Vent and Screw Vent Implant Systems originally cleared in K011028, K013227, K061410, K072589, K101977, and K111889. The new Zimmer 3.1mmD Dental Implant System is substantially equivalent to predicates devices relative to material, general design features, as well as design and manufacturing process. The differences are the implant/abutment interface, platform sizes and the implant diameter which are similar to predicate device 2 and predicate device 3.

6. Technological Characteristics

Table 1: General Implant Device Comparison

Feature	**New Device 1** Zimmer 3.1mmD Implant	**Predicate 1** Tapered Screw-Vent Implant	**Predicate 2** Screw-Vent Dental Implant	**Predicate 3** Ospol Dental Implant System
Implant Interface	Internal Hex Conical Connection	Internal Hex	Internal Hex	Conical Connection
Lengths	8mm, 10mm, 11.5mm, 13mm, 16mm	8mm, 10mm, 11.5mm, 13mm, 16mm	8mm, 10mm, 13mm, 16mm	8.0mm, 10mm, 12mm 15.0mm
Diameters	3.1mm	3.7 mm, 4.1 mm, 4.7mm, 6.0mm	3.3mm, 3.7mm, 4.7mm	4.0mm
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	Commercially Pure Titanium
Collars	Machined surface and texture, with grooves or Texture to the top with grooves	Machined Surface and Texture or Machined surface and texture, with grooves or Texture to the top with grooves	Machined Surface and Texture	Ospol Surface Texturing (Oxidized + Ca^{+2})
Thread Pattern	Triple lead threads	Triple lead threads	Single Lead	Single Lead
Surface Characteristics	MTX Surface	MTX Surface and MP-1 HA	MTX Surface and MP-1 HA	Ospol Surface Texturing (Oxidized + Ca^{+2})

Table 2: General Prosthetic Device Comparison

Feature	**New Device 2** 2.9mm Angled Abutment	**Predicate 4** Zimmer Dental Inc. 20° Angled Abutment
Implant/Abutment Interface	Internal Hex, Friction fit Conical Connection, Friction fit	Internal Hex, Friction fit
Abutment Angles	20°	20°
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI
Method of Attachment	Retaining screw	Retaining screw
Feature	**New Device 3** 2.9mm Angled Abutment, Straight Hex	**Predicate4** Zimmer Dental Inc. 20° Angled Abutment
Implant/Abutment Interface	Straight Internal Hex Conical Connection, Friction fit	Internal Hex, Friction fit
Abutment Angles	20°	20°
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI
Method of Attachment	Retaining screw	Retaining screw
Feature	**New Device 4** 2.9mm Contour Abutment	**Predicate 5** Zimmer Dental Inc. 3.5mm Hex-Lock Abutment
Implant/Abutment Interface	Internal Hex, Friction fit Conical Connection, Friction fit	Internal Hex, Friction fit
Abutment Angles	Straight, 17°	Straight, 17°

Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm	
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	
Method of Attachment	Retaining screw	Retaining screw	
Feature	**New Device 5** 2.9mm Contour Abutment, Straight Hex	**Predicate 5** Zimmer Dental Inc. 3.5mm Hex-Lock Abutment	
Implant/Abutment Interface	Straight Internal Hex Conical Connection, Friction fit	Internal Hex, Friction fit	
Abutment Angles	Straight, 17°	Straight, 17°	
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm	
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	
Method of Attachment	Retaining screw	Retaining screw	
Feature	**New Device 6** 2.9mm Temporary Abutment	**Predicate 6** Zimmer Dental Inc. Temporary Plastic Abutment	**Predicate 5** Zimmer Dental Inc. 3.5mm Hex-Lock Abutment, Straight
Implant/Abutment Interface	Straight Internal Hex Conical Connection, Friction fit	Internal hex	Internal hex, Friction fit
Abutment Angles	Straight	Straight, 17°	Straight
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm	3.5mm, 4.5mm, 5.7mm
Material	Titanium 6Al-4V ELI	PEEK-CLASSIX™	Titanium 6Al-4V ELI
Method of Attachment	Retaining screw	Retaining screw	Retaining screw
Feature	**New Device 7** 2.9mm Ball Abutment	**Predicate 7** Zimmer Dental Inc. Screw Vent Ball Abutment	
Implant/Abutment Interface	Internal Threading	Internal Threading	
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm	
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI	
Method of Attachment	Ball abutment threads into implant	Ball abutment threads into implant	

Table 3: General Ancillary Device Comparison

Feature	**New Device 8** 2.9mm Healing Collars	**Predicate 8** Zimmer Dental TSV Healing Collars
Implant/Abutment Interface	Internal Threading	Internal Threading
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI
Method of Attachment	Healing collar threads into implant	Healing collar threads into implant
Feature	**New Device 9** 2.9mm Healing Screw	**Predicate 9** Surgical Cover Screw, Titanium
Implant/Abutment Interface	Internal Threading	Internal Threading
Platform Diameter	2.9mm	3.5mm, 4.5mm, 5.7mm
Material	Titanium 6Al-4V ELI	Titanium 6Al-4V ELI
Method of Attachment	Healing screw threads into implant	Healing screw threads into implant

7. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of fatigue and compression testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the new devices are strong enough to withstand the anticipated forces and demonstrated improvements over the predicate device(s).

Additionally, Zimmer Dental implant systems were evaluated for interactions with magnetic fields during Magnetic Resonance Imaging (MRI) in accordance with the FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment and ASTM F 2182: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging. This was done to determine the presence of the dental implant or abutment poses no additional restrictions on MRI beyond those that would otherwise occur for the patient.

8. Clinical Testing:

No clinical testing was performed. Non-clinical testing was used to support the decision of substantial equivalence.

9. Conclusion:

Based on our analysis, the devices are substantially equivalent to their predicates.